

510(K) Summary

Section 5

Traditional 510(k) Summary Report

Submitter: Medsource International, LLC
5346 Shoreline Drive
Mound, MN 55364

JUL 11 2012

Contact Person: Jennifer Ness, Quality and Regulatory Affairs Manager
5346 Shoreline Drive
Mound, MN 55364
Phone: 952-241-8318

Date Prepared: April 19, 2012

General Information:

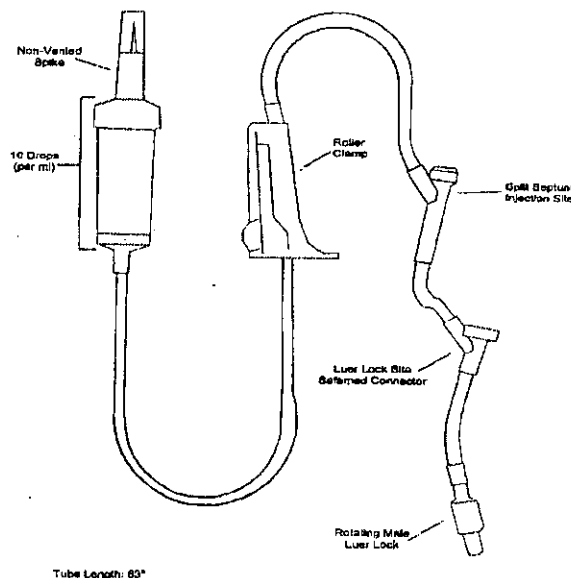
- Common or Usual Name: Set, I.v. Fluid Transfer
- Proprietary Name: MedSource IV Administration Set
- Product Code: LHI
- Panel: General Hospital
- Classification: Class II
- Regulatory Reference: 21 CFR §880.5440
- Single Use: Yes
- Sterile: Yes
- Packaging Materials: pouch made of High molecular high-density polyethylene

Indication for Use: The MedSource IV Administration Set is designed to administer parenteral fluids from a container to a vascular system through a needle or catheter inserted into a vein.

Description of the Device Design:

The MedSource IV Administration Set is a sterile, single use intravascular administration set used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein. The device includes:

1. Guard for Closure
2. Closure Piercing Device (spike)- Vented with Drip flow rate (either 10, 15, or 60 drops/mL
3. Housing for air-vent with filter
4. Drip Chamber
5. Fluid Filter
6. Tubing
7. Flow Regulator
8. Injection Site (Y-site,



- Needleless)
9. Male Luer Lock Fitting
 10. Protective Cap for Male Fitting

Patient Contact

The MedSource IV Administration Set does not come into direct contact with a patient.

Substantially Equivalence Summary:

The MedSource IV Administration Set is substantially equivalent to the Angletouch IV Administration Set (K012189).

Comparison Point	Predicate Device	Subject Device	Result of Comparison
	Angletouch IV Administration Set (K012189).	<u>MedSource IV Administration Set</u>	
Intended Use	To Administer parenteral fluids/ medication into the patient's intravascular system	Designed to administer parenteral fluids from a container to a vascular system through a needle or catheter inserted into a vein.	Substantially equivalent
Technological Characteristics (Materials of Construction, Dimensions, Performance In)	Conforms to ISO 8536-4	Conforms to ISO 8536-4	Technological Characteristics- Substantially equivalent
	PP, ABS, HDPE, PVC, PP, Latex,	Poly-Propylene, ABS, PVC, HDPE+Nylon, Silicon, HDPE (all material of not made of natural latex)	Materials of construction- substantially equivalent
	Use to administer parenteral fluids at 20 drops per ml	Used it administer parenteral fluids at either 10 drops/ml, 15 drops/ml or 60 drops/ml	Performance- substantially equivalent
	The product is a Single Use Sterile Infusion Set for Medical Use	Product is a single use sterile infusion set for medical use	Description of device- substantially equivalent
Instructions for Use	Disinfect inlet of solution container, remove set fro	Prepare IV container, Remove set from	Substantially equivalent

	<p>pouch and close the air vent and roller clamp respectively. Remove spike protector from spike, insert spike into solution container, hang container, squeeze drip chamber to fill approximately half full, remove protector from Luer lock adaptor, Open the air vent and roller clamp and solution to expel air from set, close roller clamp and attach set to access device, adjust flow wit roller clamp, check maintenance for proper flow rate a regular intervals.</p>	<p>pouch and close roller clamp, Remove spike protector from spike, Insert spike into container, Hang container, fill drip chamber by squeezing until approximately half full, remove protector from adaptor, open roller clamp, prime set and purge air from tubing, close roller clamp until roller meet bottom of frame, attached adapter to venipuncture device, adjust fluid flow with roller clamp, check maintenance of proper flow rate at regular intervals.</p>	
--	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--

Conclusion: From the comparison above, it is observed that the MedSource IV Administration Set is found to be substantially equivalent to the Angletouch IV Administration Set (K012189).

Discussion of the Device Characteristics:

The MedSource IV Administration Set is a medical device used for introducing parenteral fluids into the human body. It is a device by which parenteral fluids are entered directly into the vascular system, thereby yielding immediate results for the patients. Since fluids are parenterally entered into body by vein puncture; utmost safety has to be ensured. The sterile IV set is made up different components made up from ABS, PVC, PP, LDPE, HDPE etc. It also consists of an injection site that is not made with natural rubber latex and the needle is made of Stainless steel tube. The product is such that it meets the standard requirement and has no negative effect on the health of the patients or users. Key parts of the product including assembly and packaging are manufactured in class10,000 clean rooms following recognized consensus standards as listed below:

Standard	Title
ISO 8536-4:2004	Infusion Equipment for Medical Use: Part 4 Infusion set of single use, gravity feed
ASTM F1982-07:2009	Standard Guide for Accelerated Aging of Sterile Carrier Systems for Medical Devices
ISO 954-1 :1986	Conical Fitting with a 6%(Luer) taper for syringe needles and certain other medical equipment: Part 1- General Requirements

ISO 954-2: 1998	Conical Fitting with a 6%(Luer) taper for syringe needles and certain other medical equipment: Part 2 Lock Fittings
EN 980: 2008	Symbols for use in the labeling of Medical Devices
ISO 11138:2006	Sterilization of Health Care Products-Biological Indicators: Part 1 General Requirements
BS EM 556-1:2001	Sterilization of Medical Devices: Part 1 requirements for terminally sterilized medical device to be designated "sterile"
ISO 11135: 2007	Sterilization of Health Care Product- Ethylene Oxide: Part 1 Requirements for development, validation, and routine control of sterilization

Identification of the Risk Analysis Method:

Risk analysis was performed per internationally recognized consensus standard, ISO 14971:2007, below is the summary of the results and actions taken to mitigate those risks.

Identified Risk	Recommended Mitigation Measures
Device Malfunction	Complete Bench Testing
Adverse Tissue Reaction	Biocompatibility Testing
Infection	Sterility Testing, Microbial Ingress Testing, Clinical Use Testing
Improper Use	Labeling

Summary of Performance Testing Characteristics:

	Submission Device ↓	Predicate Device ↓
Comparison Point ↓	MedSource IV Administration Set	Angletouch IV Administration Set (K012189)
Chemical Tests		
Clarity	Meets stated specification for material	Clear
Color	Meets stated speciation for each material	Meets stated speciation for each material
Odor	Odorless	Odorless
pH	4.5-7.5	4.5-7.5
Acidity/ Alkalinity	NMT 1 ml of 0.01MNaOH / HCl Solution	NMT 1 ml of 0.01MNaOH / HCl Solution
Heavy Metals	NMT 1	NMT 1
Oxidizable Matter	NMT 2ml	HMT 2mL
No Volatile Matter	NMT 5	NMT 5
Absorbance	NMT 01 in wavelength range 250-320nm	NMT 01 in wavelength range 250-

		320nm
Biological Tests		
Sterility	Sterile ETO	Sterile ETO
Pyrogen	Non pyrogenic	Non pyrogenic
Toxicity	Non toxic	Non toxic
Physical Tests		
Integrity	no sign of leakage from any join when pressure of 50ka (500mbar) above atmospheric pressure	no sign of leakage from any join when pressure of 50ka (500mbar) above atmospheric pressure
Flow-rate	the complete set should deliver not less then 1000 ml of a 0.9% NaCl solution in 10 minutes under static head of one meter.	Not less than 100ml/min
Tensile	15N for 15 seconds	15N

Conclusion: The results in the above table demonstrate that the MedSource IV Administration Set performance meets or exceeds the performance of the predicate device.

Biocompatibility:

The MedSource IV Administration Set is comprised of identical materials that are processed by identical manufacturing methods as used in a predicate, Angletouch IV Administration Set (K012189), with the same type and duration of patient contact, therefore per Guidance Document, “**Blue Book Memo, G95-1, Use of International Standard ISO-10993, and Biological Evaluation of Medical Devices Part 1: Evaluation and Testing**” biocompatibility testing is not required.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

MedSource International, LLC.
Ms. Jennifer Ness
Quality and Regulatory Affairs Manager
5346 Shoreline Drive
Mound, Minnesota 55364

JUL 11 2012

Re: K120424
Trade/Device Name: MedSource IV Administration Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: June 25, 2012
Received: June 27, 2012

Dear Ms. Ness:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

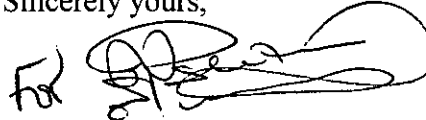
<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Anthony D. Watson', is written over a circular stamp or seal.

Anthony D. Watson, B.S., M.S., M.B.A.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120424

Device Name: MedSource I.V. Set

Indications For Use: The MedSource IV Set is designed to administer parenteral fluids from a container to a vascular system through a needle or catheter inserted into a vein.

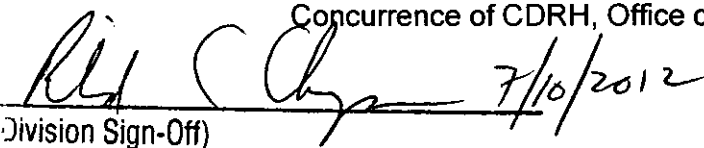
Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

 7/10/2012
Division Sign-Off)

Division of Anesthesiology, General Hospital
Direction Control, Dental Devices

510(k) Number: K120424

Page 1 of 1